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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,236	05/09/2002	Jennifer L. Hillman	PF-0659 USN	8859

7590 12/04/2003

Incyte Genomics Inc
Legal Department
3160 Porter Drive
Palo Alto, CA 94304

EXAMINER

FIELD, TAMMY K

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 12/04/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary

Application No.

09/889,236

Applicant(s)

HILLMAN ET AL.

Examiner

Tammy K. Field

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 2, and 15 are drawn to an isolated polypeptide of SEQ ID NO: 1-2 and pharmaceutical composition thereof, 1st special technical feature (*i.e.*, 1st product) for a polypeptide and pharmaceutical composition of SEQ ID NO: 1-2.

Group II, claim(s) 3-7, and 10-11 are drawn to an isolated polynucleotide of SEQ ID NO: 3-4, transformed cell, and transgenic organism, 2nd product.

Group III, claim(s) 8 is drawn to a method of making the 1st product.

Group IV, claim(s) 9 is drawn to an isolated antibody, 3rd product.

Group V, claim(s) 12-14 are drawn to a method for detecting a target polynucleotide using a probe, method of using the 2nd product.

Group VI, claim(s) 16 is drawn to a method of using the 1st product.

Group VII, claim(s) 17 is drawn to another method for screening a compound for effectiveness as an agonist, using the 1st product.

Group VIII, claim(s) 18 is drawn to a pharmaceutical composition comprising an agonist compound, 4th product.

Group VIII, claim(s) 19 is drawn to a method of treating a disease associated with decreased expression of functional CIRVP, using the 4th product.

Group X, claim(s) 20 is drawn to another method for screening a compound for effectiveness as an antagonist, using the 1st product.

Art Unit: 1645

Group XI, claim(s) 21 is drawn to a pharmaceutical composition comprising an antagonist, 5th product.

Group XII, claim(s) 22 is drawn to a method for treating a disease associated with overexpression of functional CIRYP, method of using the 4th product.

Group XIII, claim(s) 23 is drawn to another method for screening s compound for effectiveness in altering expression of a target polynucleotide, using the 2nd product.

2. The inventions listed as Groups I-XIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature that appears to be like Groups I, III, VIII, and XI, is a biologically active fragment and/or immunogenic fragment (see Claim 1, c and d). The art of Jonassen, T. *et al.* 1996. (Arch. Biochem. Biophys. 330: 285-289) teach a polypeptide comprising a biologically active, immunogenic fragment of amino acid sequence of SEQ ID NO: 1-2 (residues 1-6 of rat COQ7 are 100% identical to residues 39-44 of SEQ ID: 2, see attached alignment and corresponding amino acid sequence). Therefore, unity of invention is not fulfilled because there is not a technical feature that is "special", in that the technical feature does not define a contribution over the art. Thus, the 1st method of making and using the 1st product are kept apart. As such, the polypeptide lacks unity of invention with each of the nucleotide(s) of SEQ ID NO: 3-4 encoding the polypeptides of SEQ ID NO: 1-2 (Group II), the antibody (Group IV), agonist (Group VIII), or antagonist (Group XI) that may bind to SEQ ID NO: 1-2 (Group III). Each of Groups V-VII, VIII-X, XII-XIII represent different methods of using or making the first product or different methods of using products 2nd to 5th as defined supra. Thus, should any of these Groups be elected, they will be examined only to the extent that they read on the product feature recited in the Group as defined above.

Art Unit: 1645

As to Groups I-XII, the polypeptides of SEQ ID DO: 1-2, nucleotides (made of nucleic acids) encoding the polypeptides (made of amino acids) of SEQ ID DO: 1-2, and antibody (property of binding to antigen) defined as the 1st to 3rd products supra, lack a common structural feature/common core sequence. It is noted that Claims 18 and 21 are described in terms of function only. Should Applicants elect Group IV and inform the USPTO that the antibody acts an agonist then, Group VIII will be examined with Group IV. Should Applicants elect Group IV and inform the USPTO that the antibody acts an antagonist then, Group XI will be examined with Group IV. Each of the polypeptides, nucleotides encoding the polypeptides of SEQ ID DO: 1-2, and antibody fail to share a common property or activity. As such, each of the different products recited as 1st to 3rd supra lack a corresponding technical feature and by definition do not meet the requirements of PCT Rule 13.2. Further, in the instant case, the claims recite different methods with different active steps that relay upon five different technical features (*i.e.* products) and therefore, these methods also lack unity of invention because they lack a technical feature in common within the meaning of PCT Rule 13.2.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

3. Applicants are advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Art Unit: 1645

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tammy K. Field whose telephone number is (703) 305-4447.

The examiner can normally be reached on Monday-Friday from 7am-4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909.

Papers relating to this application may be submitted to Technology Center 1600 Group 1640 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular communications and After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Tammy K. Field

November 25, 2003


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600